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FDA-They Lie – They Cheat – They Work for the Drug Dealers

Editors Note: The FDA has become the enemy of the people.

They are so corrupt and influenced by the drug dealers and staffed by drug pushers that they can not see the folly of their ways.

The drugs they approved for safety have killed millions in the last 10 years alone. This is what they admit to.

Hospitals are cesspools of MRSA infection – the kind we can not cure. They kill millions.

These hospital infections kill more people than AIDS, Breast Cancer and car accidents – every single year!

The legal drug dealers and their cohorts in the hospitals kill, they lie, they cheat, they coverup and they have been convicted of crimes against humanity by US Federal Courts. But the madness goes on...and on...and on! They now refuse to publish the truth about the drugs and the hospital infections which kill millions of Americans.

Stop the madness. Call Congress. Demand that pharmaceutical companies and hospitals must publish all they data – both good and bad. Everything is better in the light of day. We are losing the war on cancer.

We need the truth. Millions are dying.

For the truth contact...

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Drug Safety Panel Is Criticized by Grassley

Efforts to Protect Consumers at Risk, Say Senator, FDA Official

Washington Post Wednesday, June 8, 2005 By Marc Kaufman

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The new drug safety board established by the Food and Drug Administration to restore confidence in the nation's drug supply will actually set back efforts to improve the safety of the medications Americans take and will not make it any easier to take dangerous drugs off the market, an FDA whistle-blower and a key senator said.

FDA safety officer David Graham said that after reviewing the makeup and structure of the Drug Safety Oversight Board, he concluded that the panel is "severely biased in favor of industry" and that "the FDA cannot be trusted to protect the public or reform itself."

"Ironically, drug safety in the U.S. is worse off today than it was in November," Graham added in an interview. That was when Graham, a longtime FDA safety reviewer, sharply criticized his agency's record during a Senate Finance Committee hearing into the abrupt withdrawal of the arthritis painkiller Vioxx after a study found it had harmful heart effects.

Today, committee Chairman Charles E. Grassley (R-Iowa) plans to issue his own critique of the board. In a letter to acting Commissioner Lester M. Crawford, Grassley said that the makeup of the safety oversight panel led him to conclude that "what we have here is nothing more than the status quo."

Grassley's and Graham's criticisms indicate that Congress may not be satisfied with the FDA's steps and may press for action on pending legislation to create a more independent drug safety office.

The FDA announced the 15-member board last fall in part to identify and review emerging drug safety issues that Graham and others said were not being treated seriously enough; it was formally established last month. It consists largely of FDA managers, with some input from officials of the National Institutes of Health and of the Department of Veterans Affairs.

The attacks on the panel come as a steady flow of bad news about safety problems with popular drugs has given rise to competing initiatives designed to reassure the public. The congressionally chartered Institute of Medicine is holding a public meeting today to begin an FDA-requested study of its safety procedures, and Congress is considering bills that would more aggressively address drug safety.

Other administration officials have also proposed their own ideas. Last week, Medicare Administrator Mark B. McClellan floated a plan to use billing and health care information collected from Medicare beneficiaries to create a more effective surveillance system for prescription drugs on the market. The current voluntary system for reporting serious drug reactions is believed to capture only 10 percent of actual cases. FDA officials said the initiative looks promising and that they are working with Medicare on it.

Janet Woodcock, FDA acting deputy commissioner for operations, declined to respond to Grassley's letter or Graham's comments, but she defended the safety board as useful and independent. "The safety board will be able to meet quickly, deliberate and make some



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strong recommendations if needed," she said. "They will be moving issues up and down on the scale of urgency."

For Grassley and Graham, the big problem with the safety oversight board is who will sit on it. In his letter, Grassley said 11 of the 15 voting positions on the board are filled by senior managers of the FDA's Center for Drug Evaluation and Research, the same office responsible for reviewing and approving new drugs. The safety board was established, in part, to make the safety review process more independent of the new drug review process -- an acknowledgment of sorts that officials who approve a drug for sale may be reluctant to see it taken off the market because they tend to be more focused on the potential benefits new drugs can bring.

Woodcock said the board will not include any decision makers involved with individual drug approvals and only a few of the supervisors who oversee them. She said its members will not be beholden to the drug center and will have little to do with new drug approvals.

In his letter, however, Grassley asked: "Where are the people responsible for post-marketing surveillance who have allegiances only to post-marketing safety and the public's well-being, and not to the drugs that they helped put on the market in the first place?"

He and Graham also criticized FDA's decision to keep most of the board's safety deliberations private, especially "at a time when the agency should be making every effort to improve transparency and accountability," Grassley said.

Graham noted that before he testified in November, he turned down an invitation from Crawford to play a central role in reorganizing the drug safety program, fearing that it would constrain his ability to criticize the agency.

A posting on the FDA Web site last month confirmed that most of the board's members will come from the center that evaluates new drugs, and its executive director will be appointed by the center's director. Any office can refer a drug safety issue to the board's director, who, in consultation with the center's deputy director, will decide whether and when the board should address it.

The operating procedures of the board require at least a two-thirds vote by its members to recommend that the FDA take action.

Grassley and Sen. Christopher J. Dodd (D-Conn.) have introduced a bill that would give drug safety oversight responsibility to a board that would have considerably more independence from FDA. Opponents of the proposal, including the trade association for the drug industry, say that they worry that an independent board will focus exclusively on a drug's risks and disregard its potential benefits.